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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 10/659,499 09/10/2003 Tarak D. Mody 4200.02 US 3594 32270 01/30/2006 **EXAMINER** VINIT G. KATHARDEKAR WARD, PAUL V PHARMACYCLICS, INC. ART UNIT PAPER NUMBER 995 E. ARQUES AVENUE SUNNYVALE, CA 94085 1624

DATE MAILED: 01/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Appl | ication No. | Applicant(s) | | |
|---|---|--|--|---|----------|--|
| Office Action Summary | | 10/6 | 59,499 | MODY ET AL. | | |
| | | Exar | niner | Art Unit | | |
| | | PAU | L V. WARD | 1623 | | |
| Period fo | The MAILING DATE of this commun or Reply | ication appears o | n the cover sheet | with the correspondence | address | |
| WHIC - Exter after - If NC - Failu Any | ORTENED STATUTORY PERIOD F CHEVER IS LONGER, FROM THE Nations of time may be available under the provisions SIX (6) MONTHS from the mailing date of this component of the period for reply is specified above, the maximum state to reply within the set or extended period for reply reply received by the Office later than three months and patent term adjustment. See 37 CFR 1.704(b). | ALLING DATE C s of 37 CFR 1.136(a). In nunication. atutory period will apply will, by statute, cause t | F THIS COMMUI no event, however, may and will expire SIX (6) N he application to become | NICATION. a reply be timely filed ONTHS from the mailing date of thi ABANDONED (35 U.S.C. § 133). | | |
| Status | | | | | | |
| 1) | Responsive to communication(s) file | ed on . | | | | |
| 2a)□ | This action is FINAL. 2b) This action is non-final. | | | | | |
| 3) 🗌 | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposit | ion of Claims | | | | | |
| 4) | 4) Claim(s) <u>1-42</u> is/are pending in the application. | | | | | |
| | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | |
| 5) | 5) Claim(s) is/are allowed. | | | | | |
| | Claim(s) is/are rejected. | | | | | |
| • — | 7) Claim(s) is/are objected to. | | | | | |
| 8) Claim(s) <u>1-42</u> are subject to restriction and/or election requirement. | | | | | | |
| Applicat | ion Papers | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) displayed to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority | under 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: | | | | | | |
| | 1. Certified copies of the priority documents have been received. | | | | | |
| | 2. Certified copies of the priority documents have been received in Application No | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| | | | | | | |
| Attachmer | nt(s) | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | | | | No(s)/Mail Date of Informal Patent Application (| PTO-152) | |
| Paper No(s)/Mail Date 6) Other: | | | | | | |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- The compounds and composition according to claim 1 of formula I.
 These are classifiable in class 540, subclass various.
- II. The method of treating according to claim 12. The claims are drawn to a method of treatment that is classifiable in class 514, subclass 12.2.
- III. The method of preparing according to claim 37. The claim is drawn to a method that is classifiable in class 540.

Inventions of Group I and Group III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make other and materially different products, such as metalloporphyrins.

Inventions of Group I and Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for using the product as claimed can be practiced with another materially different product.

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The inventions of Groups I-III are separate and patentably distinct because there is no patentable co-action among them and a reference anticipating one member will not render another obvious.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classification, a search of the eleven groups designated above would impose an undue burden upon the examiner, and restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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A telephone call was made to M. Hostetler on January 13, 2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is requested to elect a specifically disclosed species of the invention to be examined for search purposes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL V WARD whose telephone number is 571-272-2909. The examiner can normally be reached on M-F 8 am to 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James O. Wilson

Supervisory Patent Examiner,

Technology Center 1600